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THE BOARD OF PATENT APPEALS AND INTERFERENCES

AF, 617

In re Application of KRAEMER, et al

Application No.: 09/425,742

Filed: **October 22, 1999** 

Title: COMPOSITIONS FOR TOPICAL APPLICATION HAVING ANDROGENIC ACTIONS

Examiner: WELLS, Lauren Q.

Art Unit: 1617

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**REPLY BRIEF under 37 C.F.R. §1.193(b)(1)** 

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This is a reply to the Examiner's Answer dated April 20, 2004. The undersigned attorney believes that no fees are due for this submission. However, the Commissioner is authorized to charge any fees necessitated by this Reply Brief to Deposit Account No. 18-1982.

The purpose of this Reply Brief is to correct Counsel's statement of the real party in interest in the Appeal Brief filed December 15, 2003, to contest the Examiner's statement in the Examiner's Answer that all pending claims stand or fall together, and to address arguments made by the Examiner in the Examiner's Answer in support of the alleged motivation to combine the relied-on prior art.

#### **REAL PARTY IN INTEREST**

In addition to the Assignee, Aventis Pharma Deutschland GmbH, listed in the Appeal Brief as the real party in interest, the following parties may also be considered real parties in interest: ProSkelia S.A.S. of Romainville, France holds a license to this technology, and Inventors Karl T. Kraemer and Manfred Bohn may retain some rights to compensation under German inventorship laws if this application or a resulting patent are sold or commercialized.

#### **GROUPING OF CLAIMS**

The Examiner's statement on page 3 of the Examiner's Answer that "...claims 1-29 stand or fall together because appellant's brief does not include a statement that this grouping of claims does not stand or fall together and reasons in support thereof," is in error. The "Grouping of Claims" section of the Appeal Brief, page 5, states that claim 14 stands alone, claim 15 stands alone, claim 19 stands alone, claims 20 and 21 stand together, and claims 1-2, 4-8, 10-13, 16-17, 22-23, and 28-29 stand or fall together. Reasoned statements demonstrating why claims 14, 15, 19 and 20-21 stand or fall separately from the rest of the claims can be found on pages 16, 18, 19 and 20, respectively, of the Appeal Brief.

#### **ARGUMENT**

After the withdrawal of the 35 U.S.C. §112 rejection in the Examiner's Answer, all of the remaining rejections on appeal are 35 U.S.C. §103 rejections over a combination of references including Cretois (US 5,558,859) and Dubois (US 6,162,444). These §103 rejections are each improper because there is no motivation for one of skill in the art to combine the compositions of Formula I of the skin treatment of Dubois with the ceramide and/or glycoceramide and at least one vinylpyrrolidone polymer of the hair or nail treatments of Cretois. These references teach compositions for treating entirely different tissues, and one of skill in the art would not consider components of the compositions readily interchangeable.

Applicants note that the Examiner seems to agree that one of skill in the art would not equate dermatological treatments with hair or nail treatments, because he has not argued so in any part of the instant, lengthy record. Instead, the Examiner has suggested the following three possible motivations: 1) both Cretois and Dubois teach treatments for the skin, so one of skill in the art would feel free to combine their components; 2) both Cretois and Dubois teach treatments for hair, so one of skill in the art would feel free to combine their components; or 3) the Dubois composition is taught to be an anti-seborrheic agent and one of skill in the art would be motivated to add that combination to the Cretois composition because Cretois suggests the addition of anti-seborrheic agents. Each of these alleged motivations is based on factually inaccurate readings of the prior art cited.

#### Cretois and Dubois do Not Both Teach Treatments for the Skin

The broadest disclosure of the tissue to be treated with Cretois' compositions is "the exoskeletal parts." See Abstract of Cretois. In the first paragraph of the specification of Cretois, this description is further refined to "keratinous exoskeletal parts". The Examiner has repeatedly grasped

the word "keratinous" from this definition to assert that, since skin contains keratin, Cretois teaches the treatment of skin. See, for example, the second full paragraph on page 9 of the Examiner's Answer.

The Examiner ignores the fact that skin is not an "exoskeletal part." Since Cretois contains no definition of "exoskeletal parts", applicants submit the following two definitions of "exoskeleton", both taken from current, well-known medical dictionaries, as demonstration that one of skill in the medical arts would understand that term to exclude vertebrate skin:

Exoskeleton 1. Hard parts, such as hair, teeth, nails, feathers, hooves, scales, etc., developed from the epidermis in vertebrates.

Stedman's Medical Dictionary, 27<sup>th</sup> Edition, Lippincott Williams & Wilkins

**Exoskeleton** a hard structure developed on the outside of the body, as the shell of a crustacean. In vertebrates the term is applied to structures produced by the epidermis, as hair, nails, hoofs, teeth, etc.

Dorland's Medical Dictionary, 27th Edition, W.B. Saunders Company

Copies of each definition are attached as an appendix to this Reply Brief. From these definitions, it is clear that one of skill in the medical arts would understand the "exoskeletal parts" of Cretois to be distinct from the skin (or epidermis). Although the epidermis and exoskeleton are linked by the fact that the exoskeleton is produced by the epidermis, the terms "epidermis" and "exoskeleton", as used by those of skill in the medical arts, refer to distinct tissues.

Accordingly, the Examiner's premise that both Cretois and Dubois teach preparations for treating skin is in error. Therefore, the motivation to combine Cretois and Dubois suggested by the Examiner, namely that one of skill in the art would freely combine components of compositions for treating the same tissues, is inapplicable to those references.

#### Cretois and Dubois do Not Both Teach Treatments for Hair

Dubois teaches a composition that contains "... a dermatologically effective amount of at least one liposome containing a compound of the formula ...". See the abstract and column 1, lines 24-26. Accordingly, Dubois teaches compositions for use in treating the dermis, or skin. This is further pointed out in column 4, lines 42-49, which teaches that the compositions of Dubois become concentrated in the sebaceous glands of the epidermis.

However, the Examiner has repeatedly argued that since Dubois teaches "... the treatment of the epidermis for the conditions of hirsutism, androgenic alopecia and hyperilosity, which are all conditions of hair growth ...", Dubois necessarily teaches the treatment of hair. {Please note the definitions of "exoskeleton" above, which show that hair is produced by, but a distinct tissue from,

the epidermis.} The Examiner reasons that Dubois' teaching of topical treatment of skin hair-growing must necessitate contact between the Dubois composition and any hair which grows from that skin area; "... it is impossible to apply a composition to the scalp without applying a composition to the hair." See the paragraph bridging pages 9 and 10 of the Examiner's Answer.

The Examiner's reasoning fails, because it stops there. The final step of the Examiner's proof is left as an unsupported assumption. It is certainly true that topical treatment of the scalp will necessarily lead to contact between the treating composition and hair in those the undersigned likes to refer to as "the hair fortunate". However, it is an unstated and unsupported assumption of the Examiner's reasoning that one of skill in the art would consider this inadvertent contact a treatment of those hair follicles. What pharmacological effect on the inadvertently contacted hair follicle is one of skill in the art supposed to infer from the "dermatologically effective" compound of Dubois that is taught to specifically concentrate in the sebaceous glands of the skin? While Dubois does lead to an inference of contact between the Dubois composition and hair, there is nothing in Dubois that supports the assumption that the Dubois composition is an effective treatment of the hair. If this line of reasoning were valid, wouldn't one of skill in the art necessarily conclude that chewable vitamins are, in fact, an effective topical treatment of the teeth? Applicants respectfully submit that one of skill in the cosmetic and dermatological arts would not conclude that chewable vitamins are a topical treatment of teeth or that the Dubois composition is an effective treatment for any tissue other than the epidermis.

Accordingly, the Examiner's premise that both Cretois and Dubois teach preparations for *treating* hair is in error. Therefore, the motivation to combine Cretois and Dubois suggested by the Examiner, namely that one of skill in the art would freely combine components of compositions for treating the same tissues, is inapplicable to those references.

#### The Compounds of Formula I Taught by Dubois are Not Taught to be Anti-Seborrheic Agents

Cretois teaches at column 6, lines 36-44 that her compositions may additionally contain an antiseborrheic agent. The Examiner alleges that the last full paragraph of column 6 and the paragraph bridging columns 6 and 7 of Dubois can be interpreted to mean that the compounds of Dubois themselves are antiseborrheic agents and that one of skill would therefore be motivated to use the composition of Dubois as an additive to the Cretois composition. Applicants respectfully disagree with the Examiner's interpretation of those paragraphs in Dubois. As detailed in our Appeal Brief on pages 11 and 12, a more accurate reading of the combined disclosure of those two paragraphs is that only the addition of other anti-seborrheic compounds would enable use of the

Dubois composition as an anti-seborrheic agent. Accordingly, there is no motivation to combine the Dubois composition, as disclosed, with the composition of Cretois.

As shown above, none of the motivations alleged by the Examiner for one of skill in the art to combine the teachings Cretois and Dubois withstand scrutiny. Accordingly, the 35 U.S.C. §103 rejections based the combination of Cretois and Dubois must fall.

Respectfully submitted,

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Docket No.: DEAV1998/L071 US NP



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Philadelphia • Baltimore • New York • London Buenos Aires • Hong Kong • Sydney • Tokyo si bish'ŭn-izm). A morbid compulsion to body, especially the genitals, with the intent interest in the viewer.

st-bish'ŭn-ist). One who engages in exhibi-

mant). Mentally stimulating. [L. ex-hilaro, no gladden]

fisien shal). Pertaining to a branch of philosoticoncerned with the search for the meaning of the that has been extended into existential psyficilia, existence]

An exit or outlet; death. [L. fr. ex-eo, pp. -itus,

Austrian physiologist, 1846–1926. SEE Call-E. Jyr. E. plexus.

etiemal, or outward. SEE ALSO ecto-. [G. exō,

k-so-am'il-ās). A glucanohydrolase acting on a near an end of the polysaccharide; e.g., β-amy-

n cik so-an'ti-jen). SYN ectoantigen.

Ckrin). 1. Denoting glandular secretion delivered suminal surface. SYN eccrine (1). 2. Denoting a cresouwardly through excretory ducts. [exo- + G.

Coost klik, -sik'lik). Relating to atoms or groups relicistructure but not themselves cyclic; e.g., the ortoluene. Cf. endocyclic.

in Cisso-si-to'sis). 1. The appearance of migrating cells in the epidermis. 2. The process whereby mules or droplets are released from a cell; the membrane granule fuses with the cell membrane, which the secretion is discharged. syn emeiocytosis, emiocytosis. [exo- + G. kytos, cell, + -osis, condi-

tion (ek'sō-dē-vē-ā'shun). 1. syn exophoria. 2. syn

(C. so don'shē-ā). The branch of dental practice in the extraction of teeth. [exo- + G. odous, tooth]

(ck-sō-en'zīm). syn extracellular enzyme.

(C. og a-mē). Sexual reproduction by means of contion gametes of different ancestry, as in certain proto-(C. o. + G. gamos, marriage)

(exo-+ G. gamos, marriage)

Tila (eks-ō-gas'troo-lă). An abnormal embryo in

ek'so-je-net'ik), syn exogenous.

(e. so-je'nōt). In microbial genetics, the fragment of crail that has been transferred from a donor to the being homologous for a region of the recipient's enome (endogenote), produces in the homologous return analogous to diploidy. [exo + genote]

dis (eks-oj'ë-nŭs). Originating or produced outside of syn ectogenous, exogenetic. [exo- + G. -gen,

glucosi dase. A hydrolase removing terminal αglucose residues from nonreducing ends of chains, of β-D-glucose. syn acid maltase, amyloglucosidase, lucoamylase.

(eksō-le'ver). A modified elevator for the extraction loss [exo- + L. levare, to raise]

olication (1). 2. syn umbilical hernia. 3. syn omphalocout, + omphalos, umbilicus

senger RNA from that DNA, and is therefore exline into protein) at the ribosome. [ex- + on] ex·on shuf·fle. The variation in the patterns by which RNA may produce diverse sets of exons from a single gene.

ex. o. nu cle ase (ek-sō-noo'klē-ās). A nuclease that releases one nucleotide at a time, serially, beginning at one end of a polynucleotide (nucleic acid); several have been prepared from Escherichia coli, designated e. I, e. II, etc.; e. III, which removes nucleotides from 3' ends of DNA, is used in DNA sequencing. Cf. endonucle-

ex·o·pep·ti·dase (ek-sō-pep'ti-dās). An enzyme that catalyzes the hydrolysis of the terminal amino acid of a peptide chain; e.g., carboxypeptidase. Cf. endopeptidase.

Ex.o.phi.a.la (ek-sō-fi'ă-lă). A genus of pathogenic fungi having dematiaceous conidiophores with one- or two-celled annel-loconidia. They cause mycetoma or phaeohyphomycosis; in cases of mycetoma, black granules develop in subcutaneous abscesses; in cases of phaeohyphomycosis, hyaline or brownish hyphae are found in tissues. [exo + G. phialē, a broad flat vessel]

E. jeansel'mei, a fungal species found in cases of mycetoma or phaeohyphomycosis.

E. wernec'kii, a fungal species that causes tinea nigra. SYN Cladosporium werneckii.

ex-o-pho-ria (ek'so-fō'rē-ă). Tendency of the eyes to deviate outward when fusion is suspended. syn exodeviation (1). [exo-+ G. phora, a carrying]

ex o phor ic (ek-sō-fōr'ik). Relating to exophoria.

ex oph thal mic (ek-sof-thal'mik). Relating to exophthalmos; marked by prominence of the eyeball.

ex oph thal mom e ter (ek-sof-thal-mom'e-ter). An instrument to measure the distance between the anterior pole of the eye and a fixed reference point, often the zygomatic bone. SYN orthometer, proptometer, statometer. [exophthalmos + G. metron, measure]

Ex-oph-thal-mos, ex-oph-thal-mus (ek-sof-thal'mos). Protrusion of one or both eyeballs; can be congenital and familial, or due to pathology, such as a retroorbital tumor (usually unilateral) or thyroid disease (usually bilateral). SYN proptosis. [G. ex, out, + ophthalmos, eye]

endocrine e., e. associated with thyroid gland disorders. SEE Graves ophthalmopathy, Graves orbitopathy.

malignant e., relentless, progressive protrusion of the eyeballs.

ex·o·phyte (ek'sō-fīt). An exterior or external plant parasite. [exo-+ G. phyton, plant]

ex o phytic (ek-sō-fit'ik). 1. Pertaining to an exophyte. 2. Denoting a neoplasm or lesion that grows outward from an epithelial surface.

ex-o-plasm (ek'sō-plazm). syn ectoplasm.

ex o se ro sis (ek'sō-se-rō'sis). Serous exudation from the skin surface, as in eczema or abrasions.

ex-o-skel-e-ton (ek-sō-skel'ĕ-tŏn). 1. Hard parts, such as hair, teeth, nails, feathers, hooves, scales, etc., developed from the epidermis in vertebrates. syn dermoskeleton. 2. Outer chitinous envelope of an insect, or the chitinous or calcareous covering of certain Crustacea and other invertebrates.

ex·o·spore (ek'sō-spōr). An exogenous spore, not encased in a sporangium. [exo-.+ G. sporos, seed]

ex·o·spo·ri·um (ek-sō-spō'rē-um). The outer envelope of a spore. ex·os·tec·to·my (ek-sos-tek'tō-mē). Removal of an exostosis. syn exostosectomy. [exostosis + G. ektomē, excision]

ex-os-to-sec-to-my (ek-sos-tō-sek'tō-mē). syn exostectomy.

Exos to sis, pl. exos to ses (eks-os-to'sis, -sez). A cartilage-capped bony projection arising from any bone that develops from cartilage. SEE ALSO osteochondroma. SYN hyperostosis (2), poroma (2). [exo- + G. osteon, bone, + -osis, condition]

e. bursa'ta, an e. arising from the joint surface of a bone and covered with cartilage and a synovial sac.

e. cartilagin'ea, an ossified chondroma arising from the epiphysis or joint surface of a bone.

hereditary multiple exostoses [MIM\*133700], a disturbance of enchondral bone growth in which multiple, generally benign osteochondromas of long bones appear during childhood, commonly with shortening of the radius and fibula; the skull is not involved;

ex-

27<sub>th</sub> Edition

# DORLAND'S ILLUSTRATED

MERRELL DOW PHARMACEUTICALS, 1865.
LIBRARY
CINCINNATI. OH 45215

# Medical Dictionary

1988

W.B. SAUNDERS COMPANY

Harcourt Brace Jovanovich, Inc.

Philadelphia London Toronto Montreal Sydney Tokyo es in the epidermis as part of the inflammatory

ponse ponse (ek"so-de-ok"se-ri"bo-nu'kle-ās) 2 (1911) any of a sub-sub class of enzymes of the hydroclass that catalyze the hydrolysis of terminal bonds of corribonucleotides, releasing mononucleotides.

odeviation (ek"so-de"ve-a'shun) 1. exophoria. 2. exo-

centrifugal or ef-

rodontia (ek"so-don'she-ah) exodontics.

don'tics (ek"so-don'tiks) that branch of dentistry dealwith extraction of the teeth. Called also exodontia.

contist (ek"so-don'tist) a dentist who practices exo-

coenzyme (ek"so-en'zīm) an extracellular enzyme; an hayme that acts outside of the cells in which it originates. coergic (ek"so-er'jik) characterized by or accompanied by during and by which energy is released; energy releasing. Cf. middergic and endothermic.

roerythrocytic (ek"so-ĕ-rith"ro-si'tik) outside erithrocyte, a term applied to stages in the development of malarial parasites which takes place in tissue cells instead of

in erythrocytes.

rogamy (ek-sog'ah-me) [exo- + Gr. gamos marriage] pro-izoan lertilization by the union of elements that are not tenied from the same cell. Cf. autogamy (def. 1) and andogamy (def. 1).

exogastric (ek"so-gas'trik) pertaining to the external surtace of the stomach.

cogastritis (ek"so-gas-tri'tis) inflammation of the extercoat of the stomach.

orastrula (ek"so-gas'troo-lah) [exo- + gastrula] a gas-rula in which invagination is hindered and the mesentoderm

orastrulation (eks"o-gas"troo-la'shun) the evagination of the exterior (or turning inside out) of the gut due to an interference with the normal processes of gastrulation, which sin occur if the morula is cut transversely below the equator. treusually followed by a migration of mesenchyme cells into incunterior.

cgemmina (ek"so-jem/i-nah) [exo- + gemmare to bud] a suborder of endocommensal ciliate, mostly stalked protozoa ruler Chonotrichida, superorder Phyllopharyngidea) found in the shand brackish waters. They reproduce by external odding and have a relatively large, long cylindrical body with a well-developed collar.

corenetic (ek"so-jĕ-net'ik) [exo- + Gr. gennan to produce] exogenous.

cogenic (ek"so-jen'ik) exogenous.

Crenina (ek"so-jē-ni'ah) [exo- + Gr. gennan to produce]

Saliorder of ciliate protozoa (order Suctorida, subclass suctoria), most species of which are large and either solitary marine, free-living, or endocommensal organisms, and suctorial tentacles; the ome species have both prehensile and suctorial tentacles; the practically naked. The organisms reproduce by exogenous indding without invagination of the parental cortex.

of enote (eks"o-je'nōt) in bacterial genetics, the extra piece of genetic information introduced by transduction into piece of genetic information introduced by transduction into piece of genetic cell by the donor cell. Cf. endgenote.

Oceanism to produce description of the control of t

cathia (ek"sog-na'the-ah) prognathism.

omathion (ek"sog-na'the-on) [exo- + Gr. gnathos jaw]

Outphalos (eks-om'fah-los) [ex- + Gr. omphalos navel] congenital umbilical hernia. Omysium (eks"o-mis'e-um) perimysium

(eks'o-mis'e-uni)

1015(iks'on) a coding sequence in a gene; see intron. onuclease (ek"so-nu'kle-ās) [EC 3.1.11,16] any of the mes of the hydrolase class that catalyze the hydrolysis of of the hydrolase class that catalyze the ns, releasing mononucleotides. Cf. endonuclease.

exopathic (ek"so-path'ik) of the nature of an exopathy; originating outside the body.

exopathy (eks-op'ah-the) [exo- + Gr. pathos disease] a disease originating in some cause lying outside the organism; exogenous disease.

exopeptidase (ek"so-pep'ti-das) any enzyme of the hydrolase class that catalyzes the hydrolysis of a terminal peptide bond, releasing a single amino acid from that chain

exophoria (ek-so-fo're-ah) [exo- + phoria] a form of heterophoria in which there is deviation of the visual axis of one eye away from that of the other eye in the absence of visual fusional stimuli. Called also exodeviation.

exophoric (ek"so-for'ik) pertaining to or characterized by exophoria.

exophthalmic (ek"sof-thal'mik) of or pertaining to or characterized by exophthalmos.

exophthalmogenic (ek"sof-thal"mo-jen'ik) causing or producing exophthalmos.

exophthalmometer (ek"sof-thal-mom'ë-ter) ment for measuring the amount of exophthalmos; called also ophthalmostatometer, orthometer, proptometer, protometer, and statometer.

exophthalmometric (ek"sof-thal"mo-met'rik) pertaining to exophthalmometry.

exophthalmometry (ek"sof-thal-mom'e-tre) [exophthalmos + -metry] measurement of the extent of protrusion of the eyeball in exophthalmos.

exophthalmos (ek"sof-thal'mos) [ex- + Gr. ophthalmos eye] abnormal protrusion of the eyeball; called also proptosis. endocrine e., exophthalmos associated with disorder of an endocrine gland, commonly thyrotoxicosis. malignant e., the severe exophthalmos of Graves' disease in which there is marked edema and infiltration of the orbital tissues and extraocular muscles, proptosis, and stare. It was formerly attributed to overactivity of thyrotropin, and so was formerly called thyrotropic e. pulsating e., exophthalmos with pulsation and bruit, often due to aneurysm pushing the eye forward. thyrotoxic e., a mild form due to thyrotoxicothyrotropic e., malignant e.

exophthalmus (ek"sof-thal'mus) exophthalmos.

exophytic (ek"so-fit'ik) [exo- + Gr. phyein to grow] growing outward; in oncology, proliferating on the exterior or surface epithelium of an organ or other structure, in which the growth originated.

exoplasm (ek'so-plazm) plasma membrane.

exorbitism (ek-sor/bĭ-tizm) exophthalmos.

exoribonuclease (ek"so-ri"bo-nu'kle-ās) [EC 3.1.13-14] any enzyme of two sub-subclasses of the hydrolase class that catalyzes the hydrolysis of terminal bonds of ribonucleotides, producing mononucleotides.

exosepsis (ek"so-sep'sis) [ex- + Gr. sēpsis decay] septic poisoning which does not originate within the organism.

exoserosis (ek"so-se-ro'sis) an oozing of serum or exudate, as in moist skin diseases and edema.

exoskeleton (ek"so-skel'ĕ-ton) [exo- + skeleton] structure developed on the outside of the body, as the shell of a crustacean. In vertebrates the term is applied to structures produced by the epidermis, as hair, nails, hoofs, teeth, etc.

exosmose (ek'sos-mos) to diffuse from within outward. exosmosis (ek"sos-mo'sis) [ex- + Gr. osmos impulsion] diffusion or osmosis from within outward; movement outward through a diaphragm or through vessel walls. Cf. endosmosis. exospore (ek/so-spor) conidium.

exosporium (ek"so-spo're-um) the external layer of the envelope of a spore.

exostosectomy (ek-sos"to-sek'to-me) excision of an exos-

exostosis (ek"sos-to'sis) [ex- + Gr. osteon bone] a benign bony growth projecting outward from the surface of a bone, characteristically capped by cartilage. e. bursa'ta, an exostosis from the epiphyseal portion of a bone, consisting of bone and cartilaginous tissue covered by a connective-tissue capsule. e. cartilagin'ea, a variety of osteoma consisting of a layer of cartilage developing beneath the periosteum of a bone. hereditary multiple exostoses, multiple e. ivory e., a bony growth of great density. multiple exostoses, a hereditary disorder characterized by exostoses near the extremities of diaphyses of long bones, which may